



November 1, 2024

Dear Valued Supplier,

This letter contains updated and time sensitive information and should be passed along to individuals in your company managing FSMA 204 compliance. **For those not compliant, McLane will be introducing financial penalties that are outlined in this letter.** The next immediate compliance date is November 29, 2024. **Compliance dates are highlighted in yellow below.**

The information for the McLane Data request should be provided to McLane no later than Friday, November 29, 2024.

Beginning Monday, December 2, McLane will begin assessing fines of \$1,500 per week to any supplier that has not provided their responses to the below questions and / or whomever has not provided their self-identification of FDA's Food Traceability List (FTL) items via the Share-ify portal. For companies selling to Walmart, all food items will be considered FTL according to Walmart's September 2024 announcement to suppliers.

Multiple letters containing important information about McLane's efforts to prepare for compliance with U.S. Food & Drug Administration (FDA) Final Traceability Rule (commonly known as FSMA 204) have been sent to all McLane suppliers. These letters contain details to help you comply with the law.

Compliance with Federal Law & Customer Requirements

Some of our joint customers have begun to communicate their requirements for FSMA 204.

At this time, McLane is requesting that all suppliers are ready by June 30, 2025, to transmit Shipping KDE's.

Some customers have expanded beyond the FDA's Food Traceability List and requested all food items follow this standard. Customers have also placed deadlines for readiness. To fulfill both FDA and customer requirements and to ensure McLane remains compliant, **McLane will require all suppliers to complete the below Data Request.**

Uploading Data to Share-ify

As of 2023, McLane has partnered with Share-ify to manage all supplier-based requirements. Share-ify's Customer Success Team is prepared to assist McLane suppliers with providing the necessary information to be ready for FSMA 204. Each McLane supplier has been assigned a Share-ify CST member to assist them with responding to the requirements in this letter. McLane has requested that Share-ify helps you with this process.



It is our intention at McLane to make compliance with FSMA 204 as easy as possible for you and for us.

To that end, we need the following information from you:

1. Is your company subject to FSMA 204? * (Yes or No)
2. Does your company provide any FTL items to McLane (and our joint customers)? If yes, provide the following for each item:
 - a. McLane Product Code
 - b. GTIN
 - c. Product Description
 - d. Product Category
3. If yes to Question 2, Please provide a list of locations at which the FTL items are made.
 - a. Name
 - b. Complete Physical Address
4. If yes to Question 2, please provide the list of Traceability Lot Code Source References for all FTL items: (NOTE: *If you plan to provide your production location name and address on each unit produced at the manufacturer site, then you can skip this step.*)
 - a. GLN (414), or
 - b. DUNS Numbers, or
 - c. Global GAP Number, or
 - d. FDA Food Facility Registration Number, or
 - e. Other acceptable location identifier as allowed by FDA.
5. What method will you use to share your shipping Critical Tracking Events (CTE's) with McLane?
 - a. EDI / ASN
 - b. BOL and Case Label only
 - c. API or 3rd Party Service Provider

*Keep in mind that your company may not be subject to FSMA 204 but still sell FTL items. McLane would still be required to keep FSMA 204 compliant traceability records in this scenario.

Please be aware that McLane is requiring a case label that includes a GS1- 128 barcode with all Key Data Elements (KDE's). A helpful guide for formatting these labels is available here. [Click here](#).

As McLane and industry partners work on plans and rollout, we will continue to provide updates as we have them. If you have questions, please email fsma204@mcclaneco.com

Thank you, for your time and attention to the above. In the addendum is some additional information for your convenience and benefit.

Sincerely,

Jon Cox

Jon Cox
Vice President
Retail Foodservice

Chris Skelly

Chris Skelly
Senior Director
Procurement

Terry Levee

Terry Levee
Senior Director
Food Safety & Quality Assurance

Addendum

FSMA 204

As you know, the U.S. Food & Drug Administration (FDA) released their [Final Rule on Requirements for Additional Traceability Records for Certain Foods](#) in January 2023. This is referred to as the Food Traceability Rule (FTR) or “FSMA 204” (or section 204) and is one of many elements of the Food Safety Modernization Act or “FSMA.”

FSMA 204 defines traceability in a new way and requires entities in the food supply chain to maintain records for Key Data Elements (KDE’s) when a Critical Tracking Event (CTE) occurs for food items listed on the Food Traceability List (FTL) as published by FDA. The food manufacturer’s lot code will need to be linked to all CTE’s collected in the supply chain. Companies will no longer be allowed to create their own lot code for another manufacturer’s products when providing records to FDA.

Suppliers, manufacturers, distributors, and others handling FTL items in the supply chain will be required to assign a unique “traceability lot code” (TLC) to each FTL food item if one has not been previously assigned.

As a supplier, you are required to share your shipping KDEs for each FTL item you supply to McLane. Key Data Elements are dependent on the type of food and the type of event.

In general, Shipping Key Data Elements include at least the following KDE’s:

- Ship To Location (Receiving / Immediate Subsequent Recipient)
- Ship From Location
- Product Description
- GTIN
- Product Traceability Lot Code
- Quantity and Unit of Measure
- Ship Date
- Traceability Lot Code Source (TLC) or TLC Reference

For some products, date codes may also be used as a KDE.

Transmitting KDEs to McLane

As shared in previous communication, all suppliers must share their shipping KDE records for each FTL item shipped to McLane. If you are selling to our joint customer that requires more than FDA’s FTL items, then you will be expected to comply with those requests. It is our expectation that you will do the following:



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1. Validate that all shipping records are complete and accurate.
2. Provide the shipping KDE in electronic format via an Advanced Ship Notice (ASN) or other Application Program Interface **before the delivery date.**
3. Provide any physical paper records (such as a Bill of Lading (BOL)) at the time of delivery.
4. Each FTL food item must have
 - a. The Traceability Lot Code assigned and a standard TLC format should be used for all shipments from your company.
 - b. Each individual Key Data Element identified and a standard format used for each across all shipments from your company.
5. Assign a GS1 GTIN to each FTL item
6. Assign a GS1 Global Location Number (GLN) to identify your corporate, production, and shipping locations and upload the list of all GLN's to Share-ify.
7. Use GS1 compliant data carriers (i.e. GS1-128 barcode labels) to encode the Traceability Lot Code Source or TLC Source reference on two adjacent sides of all packages, unless we agree to a variance based on the type of product.
8. Use GS1's SSCC-18 pallet tag that references all TLC's on a pallet and identify all mixed pallets.
9. Use a distinctive case label to denote any product that is FTL.
10. Use a distinctive pallet label for pallets with mixed lots.
11. On the Advanced Ship Notice and the Bill of Lading, mark the FTL product and pallets with a distinctive color (using labels, color wrap, or highlighter / marker).